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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/325,819	06/04/1999	MAKOTO YAMAMORI	85765-000000	3326

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EXAMINER

GRUNBERG, ANNE MARIE

ART UNIT	PAPER NUMBER
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1661

DATE MAILED: 09/23/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/325,819

Applicant(s)

YAMAMORI, MAKOTO

Examiner

Anne Marie Grunberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 November 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Claims 1-5 are pending. Claims 6-15 were canceled.

Applicant is reminded to file substitute drawings in accordance with the draftsman's comments attached to Paper #10.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections***

#### ***Written Description***

1. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims that recite wheat starch wherein the plants from which the seed is obtained and from which the starch is made is not specified and adequately described in the specification are rejected because the inventor was not in possession of the claimed invention at the time of filing. As such, all wheat starch which has an apparent amylose content of 35% or more and is obtained from wheat endosperm that is modified to lack starch granule protein-1 (SGP-) is claimed, however all possible wheat seeds and moreover the plants that produce these seeds have not been adequately described in the specification. The specification only discloses progeny produced from crosses involving Chousen 30 or Chousen 57, Turkey 116, and Kanto 79.

In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been described by their

complete structure. (It is not realistic to expect that the "complete structure" of a plant, or even a cell, could be described. Therefore the inquiry required by this portion of the written description guidelines is interpreted to be whether the phenotype of the plant has been described from which the starch is derived.) In this case, the few disclosed embodiments are not representative of the enormous number of products claimed. The claims encompass starch from every possible seed obtained from any wheat plant wherein the endosperm has been modified to lack SGP-1 and which has an apparent amylose content of at least 35%. Wheat plants from which seed used for starch is derived have many phenotype traits, which vary independently, so millions of possible phenotypes are possible and the starch from all of these are claimed. The specification discloses only starch made from the seed of progeny from crosses involving the parents Chousen 30 or Chousen 57, Turkey 116, and Kanto 79, but not the total population of starch obtained from endosperm of a wheat seed which is modified to lack SGP-1 and which has an apparent amylose content of at least 35% which is claimed. Next, then, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics. It is not possible to adequately describe the claimed products because there may be an infinite combination of parents that when crossed will provide progeny containing such an amylose content. Furthermore, there may already exist other wheat seeds that naturally contain such null alleles. One skilled in the art would not have been able to predict all of the resulting phenotypes of plants that could possibly produce such starch. The limited disclosure in the specification is not deemed sufficient to reasonably convey to one skilled in the art that Applicants were in possession of the huge genera recited in the claims at the time the application was filed. Thus it is concluded that the written description requirement is not satisfied for the claimed genera.

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This rejection could be overcome by limiting the claims to starch derived from progeny of Chousen 30 or Chousen 57, Turkey 116, and Kanto 79 wheat described in the specification.

2. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to starch obtained from progeny of Chousen 30 or Chousen 57, Turkey 116, and Kanto 79, does not reasonably provide enablement for claims broadly drawn to starch obtained from any wheat plant that has seed with an apparent amylose content of at least 35%. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification only provides guidance for obtaining starch having an amylose content of at least 35% made from crossing Chousen 30 or Chousen 57, Turkey 116, and Kanto 79. No guidance is provided regarding obtaining starch from any other wheat plant having seed that has an apparent amylose content of 35% or more. In contrast, the claims are broadly drawn to all starch having an apparent amylose content of at least 35%.

Given the claim breadth, unpredictability as defined in MPEP 2164.03 and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to produce starch from any wheat seed other than the seed produced by crossing Chousen 30 or Chousen 57, Turkey 116, and Kanto 79.

3. Claims 1-5 remain rejected under 35 U.S.C. 112, first paragraph for the reasons stated in the last office action.

Applicant states that the deposit requirement has been met because the seeds have been deposited in the genebank of the National Institute of Agrobiological sciences. However this depository is not an accepted IDA (see MPEP 2405). There are two ways in which this 112 enablement rejection can be overcome: by proving that the material is known and readily available, or by deposit as described in the last Office Action. Since the material has not been deposited in the appropriate manner, the Examiner assumes that the Applicant is relying on 37 CFR 1.802(b) which states that biological material need not be deposited if it is known and readily available to the public.

Applicant provides a certificate certifying that seeds of the parent varieties were deposited in a genebank. The certificate further certifies that the seeds were tested for viability and found viable, that the seeds will be preserved at least until 2030 A.D., and that the seeds are publicly available. Applicant further provides information pertaining to the Genebank.

This information has been considered, but is not deemed adequate for the following reasons. A deposit may not be required if the biological material is both known and readily available to the public - neither concept alone is sufficient. A material may be known in the sense that its existence has been published, but is not available to those who wish to obtain that particular known biological material. Likewise, a biological material may be available in the sense that those having possession of it would make it available upon request, but no one has been informed of its existence (MPEP 2401.01).

In *Ex parte Humphreys*, 24 USPQ2d 1255 (Bd. Pat. App. & Int. 1992), the Board held that a deposit of bacteria at the John Innes Institute did not provide availability to the public. Even though in this case, Applicants were able to prove that others were able to obtain the

material from the establishment prior to and after the present filing date, it did not establish that upon issuance of a patent that such material would continue to be accessible to the public. In this case, the Applicants did not make of record any of the facts and circumstances surrounding their obtention of material from the John Innes Institute, nor was there any evidence as to what the policy would have been upon issuance of a patent. There was no indication on the record that the Institute would allow unlimited access to the public.

There are many factors that may be used as indicia that a biological material is known and readily available to the public. Relevant factors include commercial availability, references to the biological material in printed publications, declarations of accessibility by those working in the field, or an existing deposit made in accordance with specified rules. Each factor alone may or may not be sufficient to demonstrate that the biological material is known and readily available.

The office will accept commercial availability as evidence that a biological material is known and readily available only when the evidence is clear and convincing that the public has access to the material. The relationship between the applicant relying on a biological material and the commercial supplier is one factor that would be considered in determining whether the biological material was known and readily available. Even a deposit made under the Budapest Treaty and referenced in a United States or foreign patent document would not necessarily meet the test for known and readily available unless the deposit was made under specified rules, including the provision that requires, with one possible exception (37 CFR 1.808(b)), that **all restrictions on the accessibility be irrevocably removed by the Applicant upon the granting of the patent.** See MPEP 2404.01 for a more in depth discussion of known and readily available.

In the instant case, Applicant has not met the burden of establishing that the biological material is known and readily available to the public. The Examiner notes that the Certificate of

Wheat Seeds states that the seeds are publicly available *if required*. It is not clear what this statement exactly means nor is it clear as to what constitutes requirement.

It has also not been established that all restrictions to accessibility will be irrevocably removed by the Applicant upon the granting of the plant.

Additionally, Applicant has not made of record any of the facts and circumstances surrounding obtention of material from the Genebank nor is there any evidence as to what its policy is in this regard, either now or in the future if a patent were to issue on this application. On the record there is no assurance that the Genebank would allow unlimited access to the wheat seeds if this application were to mature into a patent.

Since Applicant has failed to overcome the 112, first paragraph rejection by depositing the seeds in accordance with the manner specified in the last Office Action and alternatively, because Applicant has failed to make a convincing argument that the biological material is **both** known and readily available, the enablement rejection is maintained.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Marie Grunberg whose telephone number is (703) 305-0805. The examiner can normally be reached Monday through Friday from 8:00 to 5:00.

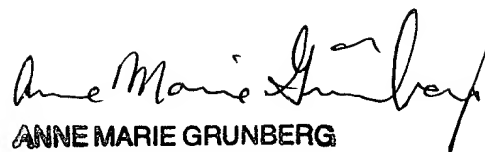
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (703) 308-4205. The fax phone number for this group is (703) 308-4242.



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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
**ANNE MARIE GRUNBERG**  
**PATENT EXAMINER**